"Express Mail" Label No. EL170265532US Date of Deposit <u>August 20, 2001</u>

Attorney Docket No.: 15270J-004743US Client Ref. No.: 209-US-CIP5C3

I hereby certify that this is being deposited with the United States Postal Service "Express Mail Post Office to Address" service under 37 CFR 1.10 on the date indicated above and is addressed to:

Assistant Commissioner for Patents

Washington, D.C. 20231

Rosemarie I. Celli

RECEIVED

AUG 2 7 2001

TECH CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Dale B. Schenk

Application No.: 09/724,319

Filed: November 27, 2000

For: PREVENTION AND TREATMENT

OF AMYLOIDOGENIC DISEASE

Examiner:

Unassigned

Art Unit:

1647

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

§1.98

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The references cited on attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/322,289, filed May 28, 1999 (Attorney Docket No. 15270J-004740US).

The publication identified as Cite No. 144 is a grant application believed to have been submitted by Victor Raso for NIH Grant No. 1 R43 AGI 5746-01 on August 29, 1997. Applicant obtained the grant proposal under the Freedom of Information Act (FOIA). It is believed that the grant proposal would not have been accessible under FOIA before April 2, 1998, but the exact date of public accessibility is not known to Applicant.

Dale B. Schenk Application No.: 09/724,319

Page 2

Applicant also cites commonly owned copending applications directed to related subject matter:

> 09/201,430 filed 11/30/98; 09/497, 553 filed 02/03/00; 09/724,477 filed 11/28/00; 09/723,927 filed 11/28/00; 09/724,762 filed 11/28/00; 09/724,102 filed 11/28/00; 09/724,489 filed 11/28/00; 09/322,289 filed 05/28/99; 09/723,713 filed 11/27/00; 09/723,760 filed 11/27/00; 09/723,384 filed 11/27/00; 09/724,495 filed 11/27/00; 09/580,015 filed 05/26/00; 09/724,940 filed 11/28/00; 09/724,961 filed 11/28/00; 09/580,018 filed 05/26/00; 09/724,552 filed 11/28/00; 09/723,544 filed 11/28/00; 09/724,273 filed 11/28/00; 09/724,551 filed 11/28/00; 09/724,288 filed 11/28/00; 09/580,019 filed 05/26/00; 09/723,765 filed 11/28/00; 09/724,291 filed 11/28/00; 09/724,921 filed 11/28/00; 09/724,929 filed 11/28/00;

09/585,817 filed 06/01/00

Dale B. Schenk Application No.: 09/724,319

Page 3

```
09/724,567 filed 11/28/00;
09/724,575 filed 11/28/00;
09/724,953 filed 11/28/00;
09/724,569 filed 11/28/00;
09/585,656 filed 06/01/00;
09/723,766 filed 11/27/00;
09/723,725 filed 11/27/00; and,
09/579,690 filed 05/26/00.
```

Applicant further cites the following commonly owned abandoned applications directed to related subject matter:

```
60/067,740 filed 12/02/97;
60/080,970 filed 04/07/98;
60/067,219 filed 12/03/97;
60/079,697 filed 03/27/98;
60/137,010 filed 06/01/99;
60/137,047 filed 06/01/99; and,
60/136,655 filed 05/28/99.
```

Applicant points out that the following applications are now commonly assigned but were previously subject to different assignment than the present application:

```
60/067,219 filed 12/03/97;
60/079,697 filed 03/27/98;
09/204,838 filed 12/03/98;
09/724,921 filed 11/28/00; and
09/724,929 filed 11/28/00.
```

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant

Dale B. Schenk

Application No.: 09/724,319

Page 4

information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

Applicant believes that <u>no fee is required</u> for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Rosemarie L. Celli Reg. No. 42,397

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8th Floor San Francisco, California 94111-3834

Tel: 650-326-2400 Fax: 650-326-2422

RLC:rnh

PA 3164970 v1

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

21

22

23

24

25

175

26

27

181

28

29

5,612,486

5,605,811

5,585,100

5,571,500

5,571,499

5,441,870

5,434,170

5,387,742

5,270,165

5,231,000

5,220,013

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Kn wn

Application Number 09/724,319

Filing Date November 27, 2000

First Named Inventor Dale B. Schenk

Group Art Unit 1647

Examiner Name Unassigned NICHOLS

(use as many sheets as necessary)

Street 1 of 11 Attorney Docket Number 15270J-004743US

\ \qua		U.S. PATENT DOCUMENTS								
A Charles and the Control of the Con	Cite No.1	U.S. Patent Document Number Kind Code² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear					
	196	6,150,091	Pandolfo et al.	11-21-2000						
	1	6,057,367	Stamler et al.	05-02-2000						
	2	5,958,883	Snow	09-28-1999						
	3	5,955,317	Suzuki et al.	09-21-1999						
	4	5,955,079	Mond et al.	09-21-1999						
	5	5,877,399	Hsiao et al.	03-02-1999						
1	6	5,869,093	Weiner et al.	02-09-1999						
	7	5,869,054	Weiner et al.	02-09-1999						
	8	5,854,204	Findeis et al.	12-29-1998						
	9	5,851,996	Kline	12-22-1998						
	10	5,849,298	Weiner et al.	12-15-1998						
_	11	5,837,473	Maggio e al.	11-17-1998						
	12	5,786,180	Konig et al.	07-28-1998						
	207	5,780,587	Potter	07-14-1998						
	13	5,753,624	McMichael et al.	05-19-1998						
	14	5,750,349	Suzuki et al.	05-12-1998						
	197	5,744,368	Goldgaber et al.	04-28-1998						
	211	5,736,142	Sette et al.	04-07-1998						
<u> </u>	15	5,733,547	Weiner et al.	03-31-1998						
	16	5,688,651	Solomon	11-18-1997						
	17	5,679,348	Nesburn et al.	10-21-1997						
 	18	5,645,820	Hafler et al.	07-08-1997						
	19	5,641,474	Hafler et al.	06-24-1997						
	20	5,641,473	Hafler et al.	06-24-1997						
	1			l						

McConlogue et al.

Seubert et al.

Mond et al.

Hafler et al.

Hafler et al.

Seubert, et al.

Andrulis, Jr.

Cordell

Van Nostrand et al.

Majocha et al.

Ponte et al.

03-18-1997

02-25-1997

12-17-1996

11-05-1996

11-05-1996

08-15-1995

07-18-1995

02-07-1995

12-14-1993

07-27-1993

06-15-1993

Examiner	Date	
Signature	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PA 3164980 v1

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO

Sheet!

Approved for use through 10/31/2002. OMB 0651-0031* U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

	C mplet if Kn wn					
Application Number	09/724,319 November 27, 2000					
Filing Date						
First Named Inventor	Dale B. Schenk					
Group Art Unit	1647					
Examiner Name	Unassigned NICHOUS					
Attorney Docket Number	15270J-004743US					

05-04-1993 5,208,036 Eppstein et al. 31 5,192,753 McGeer et al. 03-09-1993 02-16-93 32 5,187,153 Cordell et al. 10-15-1991 33 5,057,540 Kensil et al. 04-0201991 198 5,004,697 Pardridge 4,666,829 Glenner et al. 05-19-1987 34

					<u>N PATENT DOCU</u>	MENTS	, <u> </u>	
Examiner Initials*	Cite No. ¹	Office ³	eign Patent Doo Number ⁴	Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т8
	35	EP	911 036	A2		04-28-1999		
	36	EP	868 918	A2		10-07-1998		4
	37	EP	863 211	A1		09-09-1998		
	38	EP	845 270	A1		06-03-1998		
	39	EP	782 859	A1		07-09-1997		•
	40	EP	683 234	A1		11-22-1995		
	41	EP	666 080	A1		08-09-1995		
	42	EP	652 962	B1		12-16-1998		-
	43	EP	639 081	B1		11-03-1999		
	44	EP	613 007	A2		08-31-1994		
	45	EP	594 607	B1		08-27-1997		
	46	EP	561 087	B1		08-04-1999		-0
	47	EP	526 511	B1		05-28-1997		
	48	EP	506 785	B1		03-15-2000		
_ ,,	49	EP	451 700	A1	-	10-16-1991		
	50	EP	440 619	B1		01-24-1996		
	51	EP	359 783	B1		11-29-1995		U
	52	EP	276 723	B1		12-08-1993		8
	187	EP	783 104	A1		07-09-1997		
	199	PCT	00/77178	A1		12-21-2000		
	188	PCT	00/43049	A1		07-27-2000	,	-
	53	PCT	99/60024	A1		11-25-1999		-0
	54	PCT	99/60021	A2		11-15-1999		-0
	55	PCT	99/58564	A1		11-18-1999		
	56	PCT	99/06066	A2		02-11-1999		-
	57	PCT	99/27949	A1		06-10-1999		-0
	58	PCT	99/27944	A1		06-10-1999		

Examiner	Date	
Signature	Considered	,

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

+

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

Complete if Kn wn

Application Number 09/724,319

Filing Date November 27, 2000

First Named Inventor Dale B. Schenk

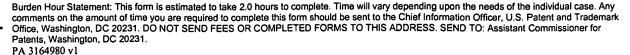
Group Art Unit 1647

Examiner Name Unassigned Old House

Sheet	E		of 11		Attorney Docket	Number	15270J-004743US	
ENT & TRAD	37							
CHI & INC	59	PCT	99/27911	A1		06-10-1	999	
	203	PCT	99/00150	A2		01-07-1	999	
	60	PCT	98/44955	A1		10-15-1	998	
	61	PCT	98/07850	A2		02-26-1	998	
	202	PCT	97/21728	A1		06-19-1	997	
	62	PCT	97/17613	A1	-	05-15-1	997	
	63	PCT	96/39176	A1		12-12-1	996	Q
	208	PCT	96/28471	A1		09-19-1	996	
	64	PCT	96/25435	A1		08-22-1	996	
	65	PCT	96/18900	A1		06-20-1	996	
	66	PCT	95/31996	A1		11-30-1	995	- 0-
	200	PCT	95/12815	A1		05-11-1	995	
	67	PCT	95/11994	A1		05-04-1	995	
	68	PCT	95/11311	A1		04-27-1	995	
	69	PCT	95/05853	A1		03-02-1	995	
	70	PCT	95/04151	A2	·	02-09-1	995	
	201	PCT	94/28412	A1		12-08-1	994	
	71	PCT	94/03615	A1		02-17-1	994	
	72	PCT	94/01772	A1		01-20-1	994	
	73	PCT	93/21950	A1		11-11-1	993	
	74	PCT	93/16724	A1		09-02-1	993	
	75	PCT	93/15760	A1		08-19-1	993	
	76	PCT	93/14200	A1		07-22-1	993	
	205	PCT	93/04194	A1		03-04-1	993	
	77	PCT	93/02189	A1		02-04-1	993	
	78	PCT	92/13069	A1	,	08-06-1	992	
	79	PCT	92/06708	A1	-	04-30-1	992	
	80	PCT	92/06187	A1		04-16-1	992	
	81	PCT	91/19810	A1		12-26-1	991	
	82	PCT	91/16819	A1		11-14-1	991	
	83	PCT	91/12816	A1		09-05-1	991	
	84	PCT	91/08760	A1		06-27-1	991	
	85	PCT	90/12871	A1	-	11-01-1	990	8-
	86	PCT	90/12870	A1		11-01-1	990	
	87	PCT	89/01343	A1	-	02-23-1	989	- B
	88	PCT	89/06242	A1		07-13-1	989	
	89	PCT	89/06689	A1		07-27-1	989	
	90	PCT	89/03687	A1	~	05-05-1	989	
	91	PCT	88/10120	A1		12-29-1	988	— B-

Examiner	Date	
Signature	Considered	

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.



EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

92

93

GB

GB

2 220 211

2 335 192

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

01-04-1990

09-15-1999

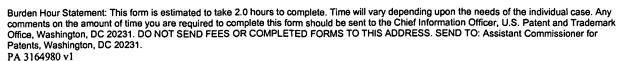
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute	for form 1449A/PTC)		Complete if Known			
				Application Number	09/724,319		
INFO	RMATION	DIS	CLOSURE	Filing Date	November 27, 2000		
STATEMENT BY APPLICANT		First Named Inventor	Dale B. Schenk				
				Group Art Unit	1647		
	(use as many she	ets as	necessary)	Examiner Name	Unassigned NICHOCS		
Sheet	4	of	11	Attorney Docket Number	15270J-004743US		

P	-
AU6 2 0 2001	
STENT & TRADES	

Examiner	Date	
Signature	Considered	

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.





^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

C mplete if Known

15270J-004743US

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Attorney Docket Number

Substitute for form 1449B/PTO

ENFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Applicati n Number 09/724,319

Filing Dat November 27, 2000

First Named Inventor Dale B. Schenk

Group Art Unit 1647

Examiner Name Unassigned No CHOCS

AU 2 0 2001

(5) 5 of 11

Sheet 5

	1	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	Т			
Examiner nitials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	т			
	94	ANDERSEN et al., "Do nonsteroidal anti-inflammatory drugs decrease the risk for Alzheimer's disease?," Neurology, 45:1441-1445 (1995).	-€			
	95	Associated Press, "Immune cells may promote Alzehimer's, a study finds," The Boston Globe (4/13/95).	-			
	96	BAUER et al., "Interleukin-6 and α-2-macroglobulin indicate an acute-phase state in Alzheimer's disease cortices," <u>FEBS Letters</u> , 285(1):111-114 (1991).	-			
	BERCOVICI et al., "Chronic Intravenous Injections of Antigen Induce and Maintain Tolerance in T Cell Recept Transgenic Mice," <u>Eur. J. Immunol.</u> 29:345-354 (1999).					
	212	BICKEL et al., "Site Protected, Cationized Monoclonal Antibody Against Beta Amyloid as a Potential Diagnostic Imaging Technique for Alzheomer's Diseases," Soc. for Neuroscience Abstracts 18:764 (1992).	-			
	176	BARD et al., "Peripherally administered antibodies against amyloid β-peptide enter the central nervous system and reduce pathology in a mouse model of Alzheimer disease," Nature Medicine, 6(8):916-919 (2000).	F			
	97	BLASS, John P., "Immunologic Treatment of Alzheimer's Disease," New England J. Medicine, 341(22):1694 (1999).	E			
	98	BODMER et al., "Transforming Growth Factor-Beta Bound to Soluble Derivatives of the Beta Amyloid Precursor Protein of Alzheimer's Disease," <u>Biochem. Biophys. Res. Comm.</u> , 171(2):890-897 (1990).	-			
	99	BORCHELT et al., "Accelerated Amyloid Deposition in the Brains of Transgenic Mice Coexpressing Mutant Presenilin 1 and Amyloid Precursor Proteins," Neuron, 19: 939-945 (1997).	E			
	100	BORIS-LAWRIE et al., "Recent advances in retrovirus vector technology," <u>Cur. Opin. Genet Develop.</u> , 3: 102-109 (1993).	-			
	101	BRICE et al., "Absense of the amyloid precursor protein gene mutation (APP717 : Val->IIe) in 85 cases of early onset Alzheimer's disease," <u>J. Neurology, Neurosurg. Psychiatry</u> , 56:112-115 (1993).	J			
	102	CHAO et al., "Transforming Growth Factor-β Protects human Neurons Against β-Amyloid-Induced Injury," <u>Soc.</u> <u>Neurosci. Abstracts</u> , 19:513.7 (1993).	 E			
	213	CHEN et al. "An Antibody to β Amyloid Precursor Protein Inhibits Cell-substratum Adhesion in Many Mammalian Cell Types," Neuroscience Letters 125:223-226 (1991).	E			
	214	DEMATTOS et al., "Peripheral Anti Aβ Antibody Alters CNS And Plasma Aβ Clearance and Decreases Brain Aβ Burden in a Mouse Model of Alzheimer's Disease," Proc. Natl. Acad. Sci. USA, 10.1073/pnas.151261398 (2001).	€			
	103	DUFF et al., "Mouse model made," Nature, 373: 476-477 (1995).	Æ			

Examiner	Date	
Signature	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Kn wn **Application Number** 09/724,319 November 27, 2000 Filing Date **First Named Inventor** Dale B. Schenk **Group Art Unit** 1647 Unassigned **Examiner Name** Attorney Docket Number 15270 L-004743US

, ,	Sheet	6	of 11	Attorney Docket Number	15270J-004743US	_/
AU6 2 0	2001					- -
	THE STATE OF THE S	104	ELIZAN et al., "Antineurofilament ar	ntibodies in a postencephalitic and idic Sciences, 59:341-347 (1983).	pathic Parkinson's disease," <u>J. Neurol.</u>	-8-
PATENT &	RAUS	105		f the β-amyloid precursor protein carry ninal mutation," <u>Neuroscience Letters</u> ,	ing the familial, Dutch-type, and a novel 152:185-189 (1993).	-
		106	FINCH et al., "Evolutionary Per	spectives on Amyloid and Inflammator eurobiology of Aging, 17(5):809-815 (1	y Features of Alzheimer Disease," 1996).	+-
		107	FISHER et al., "Expression of the am	yloid precursor protein gene in mouse 1782 (1991).	oocytes and embryos," PNAS, 88:1779-	-
		108	FLANDERS et al., "Altered expressio	n of transforming growth factor-β in Al 1569 (1995).	zheimer's disease," <u>Neurology</u> , 45:1561-	-
		210		of an anti-Aβ monoclonal antibody for i er's disease," Mol. Neurology, 9:107-1	n vivo imaging of amyloid angiopathy in 13 (1994).	
		109		uropathology in transgenic mice overe otein," Nature, 373(6514): 523-527 (1	xpressing V717F β-amyloid precursor 995).	
		215		uction of AD-type Pathology in PDAPP w York Academy of Science 920:274-6	Mice Immunized with Aβ ₁₋₄₂ ," Annals of 84 (2000).	-
		110	GANDY et al., "Amyloidogenesis in Al	zheimer's disease: some possible thei (1992).	rapeutic opportunities," <u>TiPS</u> , 13:108-113	4
		111	GASKIN et al., "Human antibodie	es reactive with beta-amyloid protein in 177:1181-1186 (1993).	Alzheimer's disease," <u>J. Exp. Med.,</u>	-
		112	GLENN et al., "Skin immu	nization made possible by cholera tox	in," <u>Nature</u> , 391: 851 (1998).	-
		113	GLENNER et al., "Alzheimer's Cerebrovascular Amyloid Protein," <u>Bio</u>	Disease: Initial Report of the Purification	on and Characterization of a Novel Communications, 120(3): 885-890 (1994).	-
		114	GLENNER et al., "Alzheimer's Disea: Protein," <u>Biochemical and</u>	se and Downs Syndrome: Sharing of A Biophysical Research Communication	A Unique Cerebrovascular Amyloid Fibril s, 122(3): 1131-1135 (1984).	
		115	GOATE et al., "Segregation of a mis-	sense mutation in the amyloid precurs disease," <u>Nature</u> , 349:704-706 (199	or protein gene with familiat Alzheimer's	ф
		116	GOZES et al., "Neuroprotective stra	tegy for Alzheimer disease: Intranasal PNAS, 93:427-432 (1996).	administration of a fatty neuropeptide,"	ф
		190	GRAVINA et al., *Amyloid β Prote	in (Aβ) in Alzheimer's Disease," <u>J. Bio</u>	I. Chem., 270(13):7013-7016 (1995).	9
		117	diptheria toxin in mice and guinea pi		d cross reacting material (CRM197) of pment and control of diphtheria vaccine 343 (1997).	-0-
		118	HAGA et al., "Synthetic Alzheimer		ction of complement C3 component by	-

Examiner	-	Date	· ·
Signature		Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents Washington, DC 20231. PA 3164980 v1



¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO

183

128

195

129

130



₽

Ð

母

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

> (use as many sheets as necessary) of

	C mpl te if Kn wn					
Application Number	09/724,319					
Filing Date	November 27, 2000					
First Named Inventor	Dale B. Schenk					
Group Art Unit	1647					
Examiner Name	Unassigned NICHOLS					
Attorney Docket Number	15270J-004743US					

AUG 2 0 HANES et al., "New advances in microsphere-based single-dose vaccines," Advanced Drug Delivery Reviews, 28: 119 97-119 (1997). VENT&T 0 120 HARDY, "Amyloid, the presentiins and Alzheimer's disease," TINS, 20(4): 154-159 (1997). 8 121 HARDY, John, "New Insights into the Genetics of Alzheimer's Disease," Annals of Med., 28:255-258 (1996). HARRINGTON et al., "Characterisation of an epitope specific to the neuron-specific isoform of human enolase recognised by a monoclonal antibody raised against a synthetic peptide corresponding to the C-terminus of β / A4-193 protein," Biochimica Biophysica Acta, 1158:120-128 (1993) HELMUTH, L., "Further Progress on a β-Amyloid Vaccine," Science, 289:375 (2000). 8 177 HSIAO et al., "Correlative Memory Deficits, Aβ Elevation, and Amyloid Plaques in Transgenic Mice," Science, 274: 4 122 99-102 (1996). HUBERMAN et al., "Correlation of cytokine secretion by mononuclear cells of Alzheimer's patients and their disease 123 stage," J. Neuroimmunology, 52:147-152 (1994). 124 8 HYMAN et al., "Molecular Epidemiology of Alzheimer's Disease," N. E. J. Medicine, 333(19):1283-1284 (1995). ITAGAKI et al., "Relationship of microglia and astrocytes to amyloid deposits of Alzheimer's disease," J. Ø 125 Neuroimmunology, 24:173-182 (1989). IWATSUBO et al., "Visualization of Aβ42(43) and Aβ40 in Senile Plaques with End-Specific Aβ Monoclonals: 192 Evidence That an Initially Deposited Species Is Aβ42(43)," Neuron, 13:45-53 (1994). JANSEN et al., "Immunotoxins: Hybrid Molecules Combining High Specificity and Potent Cytotoxicity," Immun. Rev., 126 62: 185-216 (1982). JOACHIM et al., "Antibodies to Non-beta Regions of the Beta-amyloid Precursor Protein Detect a Subset of Senile 8 216 Plaques," Am. J. of Pathology 138:373-378 (1991). KALARIA, R. N., "Serum amyloid P and related molecules associated with the acute-phase response in Alzheimer's Ð 127 disease," Res. Immunology, 143:637-641 (1992). KATZAV-GOZANSKY et al., "Effect of monoclonal antibodies in preventing carboxypeptidase A aggregation," P

Examiner	Date	
Signature	 Considered	

Biotechnol. Appl. Biochem., 23:227-230 (1996). KAWABATA et al., "Amyloid plaques, neurofibrillary tangles and neuronal loss in brains of transgenic mice-

overexpressing a C-terminal fragment of human amyloid precursor protein," Nature, 354:476-478 (1991). KONIG et al., "Development and Characterization of a Monoclonal Antibody 369.2B Specific for the Carboxyl-

Terminus of the βA4 Peptide," Annals of NY Acad. Sci., 777:344-355 (1996). LAMPERT-ETCHELLS et al., "Regional Localization of Cells Containing Complement C1q and C4 mRNAs in the

Frontal Cortex During Alzheimer's Disease," Neurodegeneration, 2:111-121 (1993).

LANGER, "New Methods of Drug Delivery," Science, 249: 1527-1532 (1990).

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231. PA 3164980 v1



EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

139

140

141

142

143

8

100s

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

ubstitute for form 1449A/PTO	C mplete if Kn wn			
	Application Number	09/724,319		
NFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	November 27, 2000		
STATEMENT BY APPLICANT	First Named Inventor	Dale B. Schenk		
	Group Art Unit	1647		

(use as many sheets as necessary) Examiner Name Unassigned

Singlet 8 of 11 Attorney Docket Number 15270J-004743US

131 LANNFELT et al., "Alzheimer's disease: molecular genetics and transgenic animal models," Behavioural Brain Res., 57:207-213 (1993).

LEMERE et al., "Mucosal Administration of Aβ Peptide Decreases Cerebral Amyloid Burden In Pd-App Transgenic Mice," Society for Neuroscience Abstracts, vol. 25, part I, Abstract 519.6, 29th Annual Meeting, (October 23-28, 1999).

LIVINGSTON et al., "The Hepatitis B Virus-Specific CTL Responses Induced in Humans by Lipopeptide Vaccination Are Comparable to Those Elicited by Acute Viral Infection," J. Immunol., 159: 1383-1392 (1997).

134 LOPEZ et al., "Serum auto-antibodies in Alzheimer's disease," Acta. Neurol. Scand., 84:441-444 (1991). MAJOCHA et al., "Development of a Monoclonal Antibody Specific for β/A4 Amyloid in Alzheimer's Disease Brain for 218 Application to In Vitro Imaging of Amyloid Angiopathy," The J. of Nuclear Med. 33:2184-2189 (1992). MASTERS et al., "Amyloid Plaque core protein in Alzheimer Disease and Down Syndrome," Proc. Natl. Acad. Sci. 217 USA, 82:4245-4249 (1985). MCGEE et al., "The encapsulation of a model protein in poly (D, L lactide-co-glycolide) microparticles of various 8 135 sizes: an evaluation of process reproducibility," J. Micro. Encap., 14(2): 197-210 (1997). 0 136 MEDA et al., "Activation of microglial cells by β-amyloid protein and interferon-γ," Nature, 374:647-650 (1995). MILLER et al., "Antigen-driven Bystander Suppression after Oral Administration of Antigens," J. Exp. Med., 174:791-137 798 (1991). MORI et al., "Mass Spectrometry of Purified Amyloid β Protein in Alzheimer's Disease," J. Biol. Chem., 8 206 267(24):17082-17088 (1992). MURPHY et al., "Development of a Monoclonal Antibody Specific for the COOH-Terminal of β-Amyloid 1-42 and Its Ð 191 Immunohistochemical Reactivity in Alzheimer's Disease and Related Disorders," Am. J. Pathology, 144(5):1082-1088 (1994). NATHANSON et al., "Bovine Spongiform Encephalopathy (BSE): Causes and Consequences of a Common Source 138 Epidemic," Am. J. Epidemiol., 145(11): 959-969 (June 1, 1997).

	144	то-сутт., Отап аррисати	
Examiner Signature		Date Considered	

New York Times National, "Anti-Inflammatory Drugs May Impede Alzheimer's," (2/20/94).

PARESCE et al., "Microglial cells influence aggregates of the Alzheimer's disease amyloid beta-protein via a

scavenger receptor," Neuron, 17:553-565 (September 1996).

PAUL et al., "Transdermal immunization with large proteins by means of ultradeformable drug carriers," Eur. J.

Immunol., 25: 3521-3524 (1995).

PRIEELS et al., "Synergistic adjuvants for vaccines," Chemical Abstracts, 120(8): pg. 652, column 1, abstract 86406t

(1994).

QUON et al., "Formation of β-Amyloid protein deposits in brains of transgenic mice," Nature, 352:239-241 (1991).

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PA 3164980 v1

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

s box +

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

C mpl te if Kn wn			
Application Number 09/724,319			
Filing Date	November 27, 2000		
First Named Inventor	Dale B. Schenk		
Group Art Unit	1647		
Examiner Name	Unassigned NICHOLS		
Attorney Docket Number	15270J-004743US		

0 200	n 😂			
-0	A Signal And Andrews	145	RASO, "Immunotherapy of Alzheimer's Disease," Immunotherapy Weekly, Abstract (April 2, 1998).	-0-
HAUS		146	ROGERS et al., "Complement activation by β-amyloid in Alzheimer Disease," PNAS, 89:1-5 (1992).	
		147	ROSSOR et al., "Alzheimer's Disease Families with Amyloid Precursor Protein Mutations," <u>Annals of New York</u> <u>Academy of Sciences</u> , 695:198-202 (1993).	-0-
		209	RUDINGER, "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence," in Peptide Hormones, J.A. Parson, ed. University Park Press, Baltimore, pp 1-7 (1976).	-8-
		189	SAIDO et al., "Spatial Resolution of Fodrin Proteolysis in Postischemic Brain," <u>J. Biol. Chem.</u> , 268(33):25239-25243 (1993).	-0
		194	SAIDO et al., "Spatial Resolution of the Primary β-Amyloidogenic Process Induced in Postischemic Hippocampus," <u>J.</u> <u>Biol. Chem.</u> , 269(21):15253-15257 (1994).	-8-
		178	SCHENK et al., "Therapeutic Approaches Related to Amyloid-β Peptide and Alzheimer's Disease," <u>J. Med. Chem.,</u> 38(21):4141–4154 (1995).	-8-
		148	SCHENK et al., "Immunization with amyloid-β attenuates Alzheimer-disease-like pathology in the PDAPP mouse," Nature, 400:173-177 (1999).	-0-
		149	SELKOE, D.J., "Imaging Alzheimer's Amyloid," Nat. Biotech., 18:823-824 (2000).	-8-
	<u> </u>	150	SELKOE, "Alzheimer's Disease: A Central Role for Amyloid," <u>J. Neuropathol. Exp. Neurol.</u> , 53(5): 438-447 (1994).	-
	· ·	151	SELKOE, "Physiological production of the β-amyloid protein and the mechanism of Alzheimer's disease," <u>Trends in Neurosciences</u> , 16(10): 403-409 (1993).	-8-
		152	SELKOE, Dennis J., "Amyloid Protein and Alzheimer's Disease," <u>Scientific American</u> , pgs. 68-78 (November, 1991).	-8-
		153	SELKOE, Dennis J., "In the Beginning," <u>Nature</u> , 354:432-433 (1991).	-8-
		154	SELKOE, Dennis J., "The Molecular pathology of Alzheimer's Disease," Neuron, 6:487-498 (1991).	-8-
		155	SELKOE, Dennis J., "Alzheimer's Disease: Genotypes, Phenotype, and Treatments," <u>Science</u> , 275:630-631 (1997).	
		156	SEUBERT et al., "Isolation and quantification of soluble Alzheimer's β-peptide from biological fluids," Nature, 359: 325-327 (1992).	4
		157	SHIOSAKA, S., "Attempts to make models for Alzheimer's disease," Neuroscience Res., 13:237-255 (1992).	4
		158	SMITS et al., "Prion Protein and Scrapie Susceptibility," Vet. Quart., 19(3): 101-105 (1997).	-

		r
Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PA 3164980 v1

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO	Complete if Known			
	Application Number	09/724,319		
INFORMATION DISCLOSURE	Filing Date	November 27, 2000		
STATEMENT BY APPLICANT	First Named Inventor	Dale B. Schenk		
	Group Art Unit	1647		
(use as many sheets as necessary)	Examiner Name	Unassigned NICHUS		

Attorney Docket Number 10 of

m R				
M F	159	SOLOMON et al., "Disaggregation of Alzheimer β-amyloid by site-directed mAb," PNAS, 94:4109-4112 (1997).	0	┝
	160	SOLOMON et al., "Monoclonal antibodies inhibit in <i>vitro</i> fibrillar aggregation of the Alzheimer β-amyloid peptide," PNAS, 93:452-455 (1996).	-	
	161	30LOMON, A., "Pro Pix (Protein Therapeutics)," University of Tennoesee Medical Center (publication date unknown).	0-	
	162	SOLOMON, B., "New Approach Towards Fast Induction of Anti β-Amyloid Peptide Immune Response," Department of Molecular Microbiology & Biotechnology, Tel-Aviv University, Ramat Aviv, Tel-Aviv, Israel (publication date unknown)."	-0-	l
<u> </u>	182	SOLOMON et al., "Inhibitory effect of monoclonal antibodies on Alzheimer's β-amyloid peptide aggregation," Int. J.	-8-	- '
	184	SOLOMON et al., "Thermal Stabilization of Carboxypeptidase A as a Function of PH and Ionic Milieu," <u>Biochem. Mol. Biol. Int.</u> , 43(3):601-611 (1997).	6	
	185	SOLOMON et al., "Modulation of The Catalytic Pathway of Carboxypeptidase A by Conjugation with Polyvinyl Alcohols," Adv. Mol. Cell Biology, 15A:33-45 (1996).		
	186	-SOLOMON et al., "Activity of mencelonal antibodies in prevention of in vitro eggregation of their antigene," abstract from Department of Molecular Microbiology and Biotechnology. Tel Aviv University, Tel Aviv, Israel (publication date-unknown).*	-8-	
<u> </u>	179	SOUTHWICK et al., "Assessment of Amyloid β protein in Cerebrospinal fluid as an Aid in the Diagnosis of Alzheimer's Disease," J. Neurochemistry, 66:259-265 (1996).	-	
	163	STOUTE et al., "A Preliminary Evaluation of a Recombinant Circumsporozoite Protein Vaccine Against <i>Plasmodium Falciparum</i> Malaria", N. Engl. J. Med., 336(2): 86-91 (1997).	0	
	164	STURCHLER-PIERRAT et al., "Two amyloid precursor protein transgenic mouse models with Alzheimer disease-like pathology," PNAS, 94: 13287-13292 (1997).	-	
	165	TANAKA et al., "NC-1900, an active fragment analog of arginine vasopressin, improves learning and memory deficits induced by beta-amyloid protein in rats," European J. Pharmacology , 352:135-142 (1998).	•] `
	166	TRIEB et al., "Is Alzheimer beta amyloid precursor protein (APP) an autoantigen? Peptides corresponding to parts of the APP sequence stimulate T lymphocytes in normals, but not in patients with Alzheimer's disease," lmmunobiology , 191(2-3):114-115 Abstract C.37, (1994).	-0-	Ļ
	167	VAN GOOL et al., "Concentrations of amyloid-β protein in cerebrospinal fluid increase with age in patients free from neurodegenerative disease," Neuroscience Letters, 172:122-124 (1994).	-	
	168	VERBEEK et al., "Accumulation of Intercellular Adhesion Molecule-1 in Senile Plaques in Brain Tissue of patients with Alzheimer's Disease," <u>Amer. Journ. Pathology</u> , 144(1):104-116 (1994).		}
	169	WALKER et al., "Labeling of Cerebral Amyloid <i>In Vivo</i> with a Monoclonal Antibody," <u>J. Neuropath. Exp. Neurology</u> , 53(4):377-383 (1994).	-0-	}
	180	WEINER et al., "ORAL TOLERANCE: Immunologic Mechanisms and Treatment of Animal and Human Organ- Specific Autoimmune Diseases by Oral Administration of Autoantigens," <u>Annu. Rev. Immunol.</u> , 12:809-837 (1994).	•	
	170	WEISSMANN et al., "Bovine spongiform encephalopathy and early onset variant Creutzfeldt-Jakob disease," Curr. Opin. Neurobiol., 7: 695-700 (1997).	0	}
		L		

Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231. PA 3164980 v1



¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.



Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

15270J-004743US

Under the Paperwork Reduction Act of 1995, no persons	are required to respond to a collection	n of information unless it contains a valid OMB control number	
Substitute for form 1449A/PTO		C mplete if Known	
	Application Number	09/724,319	
INFORMATION DISCLOSURE	Filing Date	November 27, 2000	
STATEMENT BY APPLICANT	First Named Inventor	Dale B. Schenk	
	Group Art Unit	1647	
(use as many sheets as necessary)	Examiner Name	-Unassigned N (CHOS	

Attorney Docket Number

2 0 2001 171 WEN, G.Y., "Alzheimer's Disease and Risk Factors," J. Food Drug Analysis, 6(2):465-476 (1998). 172 П WENGENACK et al., "Targeting Alzheimer amyloid plaques in vivo," Nature Biotech., 18:868-824 (2000). WONG et al., "Neuritic Plaques and Cerebrovascular Amyloid in Alzheimer Disease are Antigenically Related," Proc. 219 Natl. Acad. Sci. USA, 82:8729-8732 (1985). WOOD et al., "Amyloid precursor protein processing and Aβ42 deposition in a transgenic mouse model of Alzheimer 173 O disease," PNAS, 94: 1550-1555 (1997). Human Immunulugy & Canser Program brochure; from The University of Tenessee Medical <u>Center/ Graduate Schoo</u>l 174 of Medicine, Knoxville, Tennessee (publication date unknown).

CONSIDERED; DO HOTPRINT

Examiner	Date	
	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231. PA 3164980 v1



¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.